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Drain after elective laparoscopic cholecystectomy. A randomized multicentre controlled trial

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Abstract
Background Routine drainage after laparoscopic cholecystectomy is still debatable. The present study was designed to assess the role of drains in laparoscopic cholecystectomy performed for nonacutely inflamed gallbladder.
Methods After laparoscopic gallbladder removal, 53 patients were randomized to have a suction drain positioned in the subhepatic space and 53 patients to have a sham drain. The primary outcome measure was the presence of subhepatic fluid collection at abdominal ultrasonography, performed 24 h after surgery. Secondary outcome measures were postoperative abdominal and shoulder tip pain, use of analgesics, nausea, vomiting, and morbidity.
Results Subhepatic fluid collection was not found in 45 patients (84.9 %) in group A and in 46 patients (86.8 %) in group B (difference 1.9 (95 % confidence interval −11.37 to 15.17; $P = 0.998$). No significant difference in visual analogue scale scores with respect to abdominal and shoulder pain, use of parenteral ketorolac, nausea, and vomiting were found in either group. Two (1.9 %) significant hemorrhagic events occurred postoperatively. Wound infection was observed in three patients (5.7 %) in group A and two patients (3.8 %) in group B (difference 1.9 (95 % CI −6.19 to 9.99; $P = 0.997$).
Conclusions The present study was unable to prove that the drain was useful in elective, uncomplicated LC.

Keywords Cholecystectomy · Laparoscopy · Drainage

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Laparoscopic cholecystectomy (LC) is the current preferred method of cholecystectomy. The role of routine drainage after LC to decrease postoperative morbidity is still an issue of considerable debate. In a recent Australian survey, surgeons were evenly divided into those who used drains routinely, those who always drained, and those who never drained after LC [1]. The main reason to use drains in laparoscopic cholecystectomy is to avoid bile and blood collection requiring subsequent open procedures. However, a Cochrane Database Systematic Review found no evidence to support the use of drains in laparoscopic cholecystectomy [2]. The limitations of this review include the few randomized, clinical trials with high methodological quality and heterogeneity in the measurement of outcomes. The goal of the present multicentre trial was to assess the role of drains in LC, performed for nonacutely inflamed gallbladder. In particular, the efficacy of drain in preventing postoperative abdominal fluid collections and improving surgery outcome was evaluated.

Materials and methods

From December 1, 2009 to December 31, 2010, 270 patients aged 18 years and older were submitted to elective LC at the three participating hospitals (Hospital "P. Colombo," Velletri, Italy; University of Rome "La Sapienza", Polo Pontino, Terracina, Italy; Obafemi Awolowo University, Ile-Ife, Nigeria). Patients with acute cholecystitis, cholangitis, or pancreatitis were not included. If intraoperative common bile duct exploration or any other additional procedure were performed, patients also were excluded. Patients with evidence of concomitant choledocholithiasis were treated with preoperative endoscopic retrograde cholangiopancreatography and common bile duct clearance. After approval by local bioethics committees, informed consent was obtained preoperatively on hospital admission. The following clinical data were evaluated: age, sex, body mass index (BMI), and American Association of Anesthesiologists (ASA) risk.

Surgical management

All operations were performed by surgeons with a previous minimum experience of 50 LC. Under general anesthesia, the abdomen was insufflated with CO_2 after the introduction of the first 10-mm trocar with the Hasson technique through an infraumbilical incision. The other 10-mm and two 5-mm trocars were inserted through appropriate subxiphoid, subcostal midclavicular, and subcostal anterior axillary incisions. The pneumoperitoneum pressure and CO_2 flow rate were set at 10 mmHg and 2 L/min, respectively. A standard retrograde cholecystectomy with previous isolation and section between 10-mm clips of cystic duct and artery was always performed. The gallbladder was always bagged and retrieved through the umbilical port. The duration of the operation (from infraumbilical skin incision to pulling off the trocars), bile spillage, and additional complications also were recorded.

Randomization

After gallbladder removal with containing bag, the patients, who had no serious intraoperative complications, such as significant biliary and/or vascular injury or bleeding (>100 mL), were randomly allocated to undergo the placement of a drain in the subhepatic space (group A) or a sham drain (group B). Randomization was computer-generated, using numbered and sealed envelopes, which were opened in the operating room at the end of surgery before drain fixation to the skin. The polyethylene, 5.7-mm, multiparous, tube drain was threaded through the most lateral 5-mm trocar. In group B, after the surgeon inserted the drain, a nurse of the operatory room pulled out the drain outside the port, shortened the tube, and fixed the end to the skin with a tape after blocking the tip with a bead. All drains in both groups were connected to a 500-mL closed suction reservoir. This way, the operator, the patients, and the assessors were blinded to the intervention.

Postoperative monitoring

Patients were given a standard deep vein thrombosis prophylaxis. Postoperative pain was evaluated as follows: (1) parenteral diclofenac requirements were recorded after the patient was instructed to ask for pain relief liberally; (2) a visual analogue scale (VAS) [3] from 0 (no pain) to 10 (worst pain imaginable) was completed by each patient 24 h after surgery and at least 2 h after any eventual diclofenac assumption with respect to either abdominal and shoulder pain. An abdominal ultrasonography was routinely performed on the first postoperative day with the goal to detect any fluid collection. If present, the volume of subhepatic collection was calculated. Ultrasound examinations were performed using an Aloka Prosound Alpha 10® with a 1.5-MHz, convex probe by experienced radiologists.

The drain was removed 24 h after surgery, unless there was bile (any amount) or 100 mL of blood in the drain bag. In case the drain had to stay in place for bile leak, it was not removed, unless the leak had completely ceased. In case the drain had to stay in place for bleeding, it was removed when the amount was 100 mL/24 h and the patient was hemodynamically stable with stable hemoglobin (no decrease >1 g/dL). Patients were discharged on the second postoperative day, unless the drain had to stay in place for any of the reasons mentioned and/or intra-abdominal fluid collection >50 mL was detected at ultrasonographic examination and no other complications had occurred. Intra-abdominal fluid collections >50 mL were followed up with serial ultrasonographic examinations and patients were discharged if no increase was detected.

Postoperative problems and complications were recorded within 4 weeks after operation. Patients were reviewed at 1 week and 4 weeks postoperatively. An upper abdomen ultrasonography was routinely performed 1 week after surgery. Outcome assessors were unaware of patients' allocation.

Statistical analysis

The primary outcome measure was the presence of subhepatic fluid collection at ultrasonographic examination of the abdomen 24 h after surgery. Secondary outcome measures were postoperative abdominal and shoulder tip pain, use of analgesics, nausea, vomiting, and morbidity.

Sample size calculation was based on the goal of detecting a difference of 20 % in the proportion of patients

with absence of subhepatic fluid collection at postoperative ultrasonography, assuming from a previous personal series of 40 patients, submitted to elective laparoscopic cholecystectomy with drainage, that 78 % of cases showed no subhepatic collection at ultrasonography. With a type I error of 0.05 and a type II error of 0.10 for a two-tailed test, 53 patients per group were required.

Pearson χ^2 test was used for categorical data. A 95 % confidence interval (CI) on the difference in proportions was calculated. The Mann-Whitney *U* test was used to compare not normally distributed samples. All tests were two-tailed, and the level of significance was 0.05. All data were compiled by an independent participant unaware of patients' allocation, and the results were analyzed using Medcalc® version 7.3 (Frank Schoonjanas, Broekstraat, Belgium).

Results

The profile of the trial is shown in Fig. 1. The number of patients who entered the study in each participating center was as follows: 39 patients in the Hospital "P. Colombo," Velletri, Italy; 35 patients in the University of Rome "La Sapienza"- Polo Pontino, Terracina, Italy; 32 patients in the Obafemi Awolowo University, Ile-Ife, Nigeria). No violation of the protocol was registered. Both groups were comparable with respect to sex, age, BMI, ASA, intraoperative spillage, mean operative time, and median postoperative hospital stay (Table 1). No significant intraoperative morbidity occurred.

Abdominal ultrasonography did not show any subhepatic fluid collection in 45 patients (84.9 %) in group A and in 46 patients (86.8 %) in group B (difference 1.9 (95 % CI, −11.37 to 15.17; $P = 0.998$). If present, median (95 % CI) subhepatic collection was 30 mL (20–40 mL) in group A and 30 mL (20–40 mL) in group B ($P = 0.779$; Mann-Whitney *U* test). All subhepatic collections disappeared at ultrasonographic examination of the abdomen, performed 1 week after surgery. Median (95 % CI) abdominal pain scores 24 h after operation was 3 (2–4) in group A and 2 (2–3) in group B ($P = 0.201$; Mann-Whitney *U* test). Median (95 % CI) shoulder pain scores 24 h after operation was 0 (0–1) in group A and 0 (0–0) in group B ($P = 0.324$; Mann-Whitney *U* test). Median (95 % CI) parenteral ketorolac consumed was 60 mL (30–60 mL) in group A and 30 mL (30–30 mL) in group B ($P = 0.126$; Mann-Whitney *U* test). Four patients (7.5 %) in group A and three patients (5.8 %) in group B suffered from nausea 24 h after operation (difference 1.7 % (95 % CI, −7.78 to 11.18); $P = 0.969$). One patient (1.9 %) in

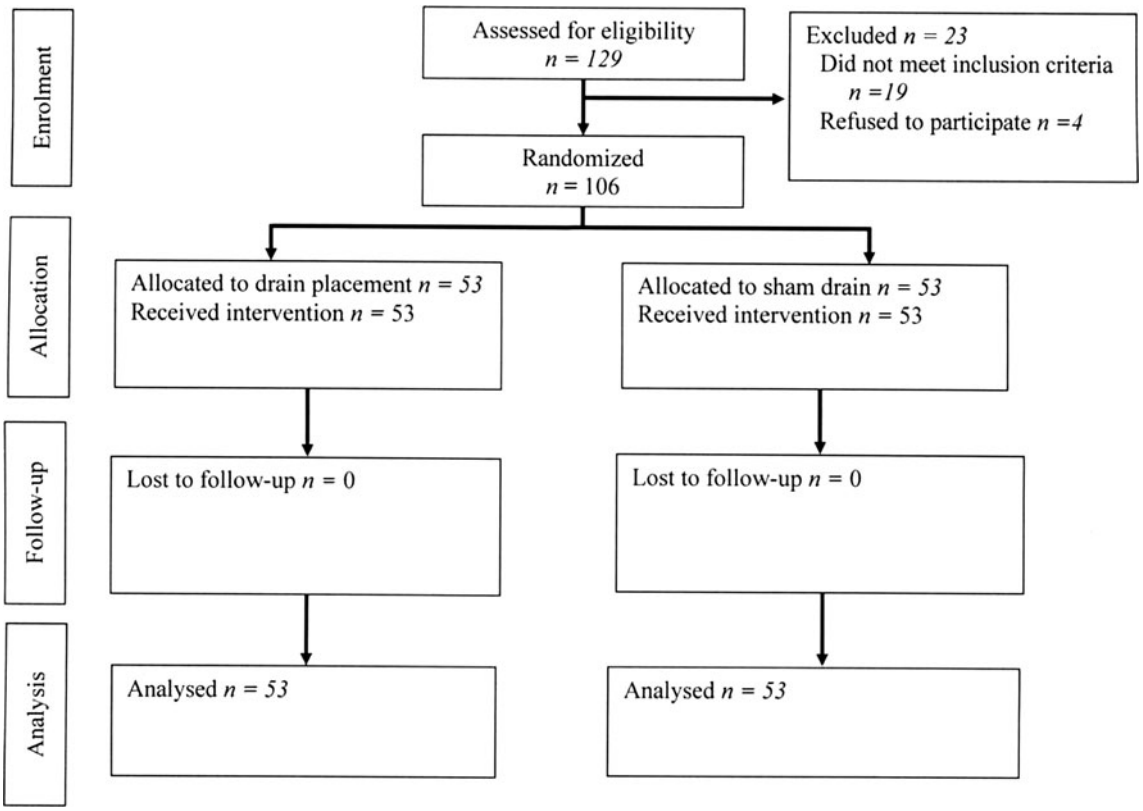

Fig. 1 CONSORT flow-chart for the randomized study

Table 1 Characteristics of patients

Characteristic	Group A ($n = 53$)	Group B ($n = 53$)
Gallbladder disease		
Cholelithiasis	49 (92.5)	49 (92.5)
Gallbladder polyp	4 (7.5)	4 (7.5)
Sex		
M	11 (20.8)	13 (24.5)
F	42 (79.2)	40 (75.5)
Mean age (95 % CI) (year)	48.6 (44.7–52.5)	47.1 (42.4–51.8)
BMI (95 % CI)	26.7 (25.5–27.9)	24.7 (23.7–25.7)
ASA		
I	27 (50.9)	22 (41.5)
II	16 (30.2)	19 (35.8)
III	10 (18.9)	12 (22.6)
Operative mean time (95 % CI) (min)	67.1 (62.8–71.3)	60.7 (55.5–65.9)
Intraoperative bile spillage	2 (3.8)	2 (3.8)
Median (range) postoperative hospital stay (days)	2 (2–7)	2 (2–10)

Values are given as number (%) of patients unless otherwise indicated

BMI body mass index; *CI* confidence interval

group A and two patients (3.8 %) in group B suffered from vomiting [difference 1.9 % (95 % CI, −4.43 to 8.23); $P = 0.997$].

Two (1.9 %) significant postoperative complications occurred. One patient in group A presented a 200-mL collection in the drain with hemodynamic instability 4 h after surgery, requiring emergency laparotomy with hemostasis of an iatrogenic lesion of the gallbladder fossa. The other patient in group B developed abrupt and intense abdominal pain with tachycardia in the second postoperative day. Ultrasonography and computed tomography scan of the abdomen showed the presence of a subcapsular hepatic hematoma involving the entire periphery of the right lobe. The patient was treated conservatively and serial ultrasonographic and tomographic examinations of the abdomen showed the progressive reduction of the subcapsular hematoma, which disappeared 5 months after surgery. Infraumbilical port-site infection occurred in five patients (4.7 %) in the entire study group. Wound infection occurred in three patients (5.7 %) in group A and two patients (3.8 %) in group B [difference 1.9 (95 % CI, −6.19 to 9.99; $P = 0.997$].

Discussion

Cholecystectomy is the second most common operation in gastrointestinal surgery after appendectomy. However, there are still limited data on the value of prophylactic drains for LC. The recent Cochrane Database Systematic Review [2] only found two studies with high methodological quality [4, 5]. Since then, only one randomized trial was published with a large number of patients enrolled and adequate methodology [6]. The present study represents a rare instance in surgery where an adequate blinding was performed.

Traditionally, drains were used for the early detection of bile leaks and any unsuspected hemorrhage and to evacuate abdominal fluid collections without the need for more invasive procedures. At present, the rate of biliary complications after LC is 0.4 % (range, 0.1–0.9 %) [7]. Postoperative hemorrhagic complications are very rare. Given the low proportion of these complications in patients submitted to elective laparoscopic cholecystectomy, it is unlikely that any trial will be powered to measure differences in these specific complications. In the present study, significant postoperative complications were rare. In particular, no postoperative bile leak was documented. Two postoperative hemorrhagic complications occurred. In one patient, the drain evidenced a significant hemorrhage. The absence of subhepatic fluid collections after cholecystectomy is strongly associated with an uncomplicated postoperative recovery [8]. The efficacy of drains to evacuate subhepatic collections may justify their use to prevent postoperative complications. However, experimental studies [9] showed that, when a drain is inserted in the peritoneal cavity that contains no fluids, it is quickly surrounded by omentum and completely occluded within 48 h. The present study was unable to prove that the drain has any influence on the presence and severity of subhepatic fluid collection after LC. Drains are supposed to be much more efficient in draining bile than other types of intra-abdominal collections. However, large series from the era of open cholecystectomy showed that most patients, who underwent laparotomy for postcholecystectomy bile peritonitis, had drains placed, suggesting that drain placement does not detect this complication effectively [10–12]. Drains also

are not effective to treat bile leak or bleeding in elective LC [6]. Moreover, a recent study showed that drains increase the occurrence of fluid in the subhepatic space after LC [13]. Possible causes are irritation from the foreign material of the drain, prevention of tissue tamponade, creation of dead space, and the effects of vacuum suction from the drain. Ultrasonographic studies clearly demonstrated that most postcholecystectomy collections remain asymptomatic and are absorbed by the peritoneum [14, 15]. In the present trial, all subhepatic collections, evidenced on the first postoperative day, were absent at 1-week control ultrasonography.

Port-site infection is a minor complication that affects 1.1–7.9 % of patients after LC [16, 17]. The use of drains seems to improve the incidence of this complication, possibly related to the presence of a foreign body [6]. However, morbidity was not increased if short-term drains were used in open cholecystectomy. Williams et al. [18] showed an increase in postoperative morbidity when Penrose drains were left longer than 48 h. In this study, the drain was routinely removed on the first postoperative day. The short permanence of the drain may account for the lack of increase in wound infections associated with the presence of a subhepatic drain. All wound infections were located at the level of the infraumbilical incision in our series. Antibiotic prophylaxis does not reduce the rate of umbilical wound infection with respect to bag extraction of the gallbladder [17]. Topical antibiotics were found to be effective in reducing this bothering complication [19].

The effect of subhepatic drain on postoperative pain is controversial. Significant reduction of postoperative pain in patient without drain insertion with respect to those with subhepatic drains was reported in the trial of Tzovaras et al. [6]. On the contrary, the study of Hawasli et al. [20] failed to find any difference. Jorgensen et al. [21] showed that the use of a suction drain in LC decreases shoulder pain by allowing carbon dioxide gas to escape with respect to passive drain. That is the reason why we chose to position a suction drain in group A. Our data were unable to prove that suction drain has any effect on either abdominal or shoulder tip pain after LC.

Postoperative nausea and vomiting has been reported with an incidence of 53–72 % after laparoscopic cholecystectomy [22]. However its incidence tends to decrease during the early postoperative recovery [23, 24]. Our data showed a low incidence of postoperative nausea and vomiting assessed 24 h after operation. The presence of drain did not influence its incidence.

In conclusion, the present study was unable to prove that the drain was useful in elective, uncomplicated LC without acute cholecystitis, cholangitis, or pancreatitis and no significant intraoperative morbidity.

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